REMARKS/ARGUMENTS

A. In the Specification

1. No changes have been made to the specification. No new matter has been added.

B. In the Claims

1. Claims 33-56 are pending in this application. Claims 33, 34, 36-41, and 43-45 have been amended to correct language, syntax, avoid the citation of the prior art, and/or point out the specific features of Applicant's invention with greater clarity. Claims 35, 42, and 46-56 are unchanged. No claims have been cancelled. No new claims have been added. No new matter has been added.

Regarding the Claim Rejections under 35 U.S.C. 112

2. Applicant acknowledges the quotation of the appropriate (second) paragraph of 35 U.S.C. 112 that forms the basis for the rejections under this section made in the office action. In response, Applicant has amended claims 34, 36-41, and 43-44 to properly amend from the correct independent claim. Applicant regrets any confusion this may have caused, and appreciates the Examiner's assuming the dependency for the purposes of proceeding with the examination process.

3. Claims 33-39 and 41-44 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Joao (6,283,761), hereinafter Joao, in view of Campbell (6,047,259), hereinafter Campbell. Applicant respectfully disagrees with the obviousness rejection in light of the amendments to claims 33-39 and 41-44, and the arguments presented below. Applicant now believes that claims 33-56 are in condition for allowance.

Before going into the arguments as to why the present invention is not made obvious by the combinations of the Joao patent in view of Campbell or Segal a discussion of the definition of a medical "chart note" should be addressed. Applicant firmly believes that the generation of

an editable medical chart note does not appear in any reference cited, nor is it suggested, nor is it old and well known in the "industry" at the time the present patent application was first filed.

The following was written by one of the applicant physicians, Dr. James Blasingame to help alleviate any confusion over what is meant by a medical chart note, especially as it relates to the present invention:

A "Medical Chart Note" refers to the recording of a patient visit which is stored in paper or electronic format. Of course traditionally and still in the majority today, most medical chart notes are stored on paper. These can be handwritten or typed. By "visit" I mean any encounter with the physician and this can include a consultation in an office, hospital or emergency room, a routine office visit for either a new or established problem, a traditional history and physical for admission to a facility, a second opinion, etc. The medical chart note is the recording of this encounter by the health care professional (usually a physician, but well be a nurse practitioner, physician assistant, dentist, oral surgeon, physical therapist, etc.) The production of a note or recording of the visit is in fact a requirement (legal and for reimbursement) and it must be accessible for something like 7 years after the visit. (I think that is the law and it may include through age 18 for children - I don't really know.) The content of the note depends on the type of visit or encounter and varies by the complexity of the problem(s). The note is supposed to reflect the nature and complexity of the visit. Certain components traditionally make up a note and I will outline them below - with all components included for a complete new patient visit, extensive consultation or admission to a facility. The reasons for completeness in initial evaluations (new patient visit to an office) or where other clinicians will be involved (admission note to hospital) is to be sure the patient's entire medical picture is understood. This prevents errors and assures the patient's general status is well understood. These notes should include all or nearly all of the components listed below (and the additional ones listed below included in the present invention). On the other hand, a follow up visit for suture removal in the office would not need to be nearly as complete. The medical chart though would contain the more inclusive note already taken and recorded upon initial contact with the patient in the hospital or office before the surgery.

Medical notes have evolved over the years to a relatively standard format which includes certain components of the patient's history in a relatively standard order. You will see the components of the present invention as we define these:

(1) Problem(s) or Chief Complaint or "Reason for admission" and others

This is a short statement as to why the patient is being seen and is traditionally the first line. Examples would be:
Problem: Pneumonia
Reason for admission: Multiple trauma

Chief complaint: Fever

(2) History of Present Illness or Subjective

This is the specific patient history as to the reason for this visit, admission, etc. This is the result of detailed questioning of the patient regarding the problem to include the timing of the onset, the symptoms, the location and nature of any pain, the workup to date and history of any important associated problems. The gathering of a baseline of information regarding the history of present illness and its presentation to the physician is the unique or central focus of our patent with relation to the present invention. That is, we have "invented" a means of gathering a detailed "History of Present Illness" for a large number of medical complaints (conditions) and a means of presenting the output of this information to the physician in a standard format. This detailed output is available to the physician before seeing the patient and serves as the basis of information from which the physician expands during the interview process with the patient. None of these listed patents do any such thing.

(3) Next come the details of the patients past medical history which the present invention also collects, but which is not unique to the present invention as there many "personal health records" that assist the patient in documenting his/her medical history.

Allergies
The patient's allergies and intolerances

Medications
The medication the patient is currently taking

Medical problems
The problems the patient already knows he has such as diabetes, hypertension, colon cancer, etc

Surgical history
The surgeries the patient has had

Family history
The list of diseases or problems that may run in the family

Social history
The patient's social setting to include marital status, living situation, smoking history, alcohol intake, safety issues, etc.

(4) Next is the "Review of Systems" (or ROS) which is a questionnaire regarding potential symptoms from various body systems.

ROS breaks down the body systems by Head and neck, chest , heart, respiratory, abdomen, neurological, etc. - and asks questions of each. Each patient has done this on a clipboard many times while waiting to be seen by a doctor in the doctor's office before an exam.

That completes the part of the chart note gathered from the patient - that is, the physician has no independent way of knowing all this - it must be extracted from the patient or a loved one, etc. The remainder of the chart note documents the information obtained by examining the patient (the physical exam) and then includes labs or studies, the physician's "Assessment" or summary or diagnosis followed by a "Plan" which outlines what is to be done next. The present invention does not claim any element regarding the physical exam, assessment, diagnosis or plan of treatment.

So far as specific, simple definition - a Medical Chart Note is the official recording of the clinical details of a patient encounter.

The main focus of the present invention is the ability to gather a very clear and thorough medical history at the disease or condition level through the use of structured clinical interviews and present that history to the physician **as a medical chart note**. This output is digital and can be presented on a computer or on paper **and is editable by the physician to complete the note**. The present application does not suggest a diagnoses - it exists to provide a thorough capture of the patient's history regarding his or her problem.

James Blasingame MD

Therefore, the element of claims 33 and 45 which includes the limitations:

> (in claim 33) a database of patient oriented structured condition-specific interviews having a series of condition-specific questions, **accessible by said patient's computers, whereby patients answer said condition-specific questions using patients computer,** prior to a doctors office visit;
>
> **a medical chart note database used to build an editable preliminary medical chart note including condition-specific clinical information, and further including the patient's specific problem, chief complaint or reason for being admitted, a history of patient's present illness, patient's past medical history, and a review of patient's current symptoms for the physician**; and likewise

(in claim 45) providing a database of patient oriented structured condition-specific interviews having a series of condition-specific questions, **accessible by said patient's computers, whereby patients answer said condition-specific questions using patients computer**, prior to a doctors office visit;

providing a medical chart note database used to build an editable preliminary medical chart note including condition-specific clinical information, and further including the patient's specific problem, chief complaint or reason for being admitted, a history of patient's present illness, patient's past medical history, and a review of patient's current symptoms for the physician; (in claim 45)

is allowable over the prior art cited.

Generating a medical chart note **is not about making a diagnosis**, but rather it is about collecting information about the patient, and in the present invention, for the first time collecting that information directly from the patient and patient's own computer for the purpose of generating an editable chart note.

For the foregoing reasons, claims 33 and 45 should be allowed.

INDEPENDENT CLAIM 33 - JOAO IN VIEW OF CAMPBELL

(A) As per claim 33, the Examiner has admitted that Joao does not expressly disclose "a networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note, comprising:

(c) a database of patient oriented structured condition-specific interviews having a series of condition-specific questions, accessible by said patient's computers, whereby patients answer said condition-specific questions using patients

computer, prior to a doctors office visit;

However, the Examiner goes on to state that this particular feature of the present invention is (a) old and well known in the art; and (b) disclosed in Campbell. Neither is supported here. First, it was not old and well know in the art to enable a patient to access a medical information system back in May of 2000, when the present application was first filed (as a provisional). In fact, this was unheard of in medical practices. There were no adequate security methods in place in which to insure hackers could not get in and see sensitive patient files. The very opposite was true. Medical practitioners and hospitals were securing medical computer systems with access available only to medical personnel. Instead, the old "patient information form on a clipboard" (as previously mentioned by inventor Dr. Blasingame) was used and is still used today by many medical practices.

Campbell is an example of this very thinking. A reading of the abstract reveals that the invention in **Campbell is directed to use by the medical personnel, that is, doctors or nurses only**. There is no suggestion of allowing the patient, on the patient's computer to play an active role. In Campbell, the user is clearly a doctor or a nurse. This is evidenced by the abstract language stating "the physical exam software guides the user through a physical exam" (done by a doctor or nurse, not the patient), and allows the "user to select a treatment protocol" and "remind(s) the user which services need to be performed and when they need to be performed." All of which are the job of the medical personnel, doctor or nurse. In Campbell, the patient never touches a computer. In that regard, there is a big difference between the system in Campbell and the present system.

Furthermore, in Campbell the system is directed toward managing an exam, diagnosis and treatment protocol. The present invention is directed toward capturing patient information from the patient, through the patient's computer, for the purpose of creating a medical chart note. There is no physical exam element, practice management element, or diagnosis element. Just data capture directly from the patient to produce a medical chart note for use by the physician.

The following points distinguish the combination of Joao with Campbell (and/or Segal):

- Both of the patents deal with attempts at making a diagnosis. That is, they are focused on suggesting diagnoses. In the present invention, we do not suggest diagnoses. We are in the patient-data-capture business. Campbell leads the user through a physical exam prompting further questions leading to diagnosis suggestions.
- The present inventive system is not in the computer diagnostics realm, or in the practice management realm.
- By patient-data-capture we mean "direct" capture from the patient straight into the office record keeping system. We are not talking about the physician or nurse capturing the data from interviewing the patient in person.
- None of these patents disclose the patient directly answering condition-specific questions in a system and having the "invention" process a medical chart note. Joao lists "at least one symptom" which is hardly a thorough medical chart note.
- We interview patients in plain English and the system translates into physician specific language or "medical lingo" for the chart.
- The present invention will feed either a standard paper chart or electronic record.
- The core of the non-obviousness of the present application is the detailed, condition-specific structured clinical interview, that is performed by the patient before a visit, the results of which are stored in a database, reformatted and presented to the physician as a generated medical chart note. This note is in medical terminology and is editable by the physician as he/she completes a full chart note.

Back in 2000, none of this was old or well known to the medical community. None of the patents cited suggest combining, and in fact, the old and well know practice in 2000 was to **keep the patient strictly away from the computer system** containing medical information. The computer was only to be operated by medical personnel.

Moreover, neither Joao, Campbell nor Segal suggest or even mention the chart note as being generated and/or editable, or using patient information obtained directly from the patient electronically to create a chart note. This was not in the realm of "the motivation of managing a medical practice."

The present invention includes a method for creating an editable medical chart note capturing a patient's medical history and condition prior to an exam for which an appointment has been scheduled with a physician, including the steps of: providing a patient with direct access to a system providing and enabling a condition-specific interview for the patient regarding the patient's medical condition wherein the content and amount of interview questions can be dynamically altered depending upon responses provided by the patient, and directly collecting the information that is provided by the patient while said patient is using his or her own computer.

Joao discloses a method whereby **the provider, not the patient**, is meant to access the central processing computer and enters data and/or information regarding the patient. This information is used for generating a diagnosis, or some other aspect of medical practice management, such as billing an insurance provider. In Campbell, the same holds true. Campbell is directed toward generating a diagnosis, and a plan for future treatment. Not so for Applicant's invention.

Applicant's invention discloses a system whereby the patient is given access information to enable the patient to gain system access via the patient's communication device. Not only does this allow the patient to access the system at the time and location of the patient's choice, it also saves the physician or provider from having to spend time and effort and use limited office space to gather this information.

Additionally, Joao does not disclose the step of providing a condition-specific interview for the patient by the server site wherein the content and amount of interview questions can be dynamically altered depending upon responses provided by the patient. Joao discloses information that can be indirectly "obtained from the various patients, individuals, providers,

payers, and/or intermediaries. While Joao discloses the ability to gain general information from patients, Joao does not disclose the step of providing an interview that is specific to the medical condition of the patient. The invention disclosed in Joao is primarily for the purpose of electronically generating medical diagnosis over an electronic network.

Combining Campbell with Joao does not make the present invention obvious because in Campbell, only medical personnel use the computer to input data and the data is directed toward making a diagnosis. It was not obvious in early 2000 to allow the patient to provide the information necessary to create an editable chart note.

Applicant's invention involves patient-data-capture aimed at producing a complete and reproducible history at a specialist's level from which the physician works to improve the quality and efficiency of the office visit.

Additionally, Campbell does not disclose the ability of the provider to enable a condition-specific interview for the patient. Therefore, the provider cannot enable the patient to complete a condition-specific interview. At most, Campbell discloses a general computer questionnaire format that must be filled in (data entered) by the doctor or nurse at the medical care provider's office. Applicant's invention discloses a system wherein **the patient can then log onto his or her own computer system and complete the specified interview at the time and location of the patient's choice, thereby directly sending the info necessary to the provider to enable generation of a medical chart note.** Campbell does not teach or even remotely suggest this novel aspect of the present invention. In fact, Campbell does not even mention a chart note being important to the software system as claimed therein.

Furthermore, the unique direct patient-data-capture capability of the present invention has solved a major problem that has always plagued the electronic medical record industry – the necessity of the physician or nurse to become a computer data entry person. Having the vast majority of the specific clinical history captured electronically from condition-specific interviews before a visit frees the physician or nurse from this repetitive and time consuming task and

allows him or her to concentrate on the patient. The routine "dumbing down" of the patient's historical information - an additional side effect encountered in physician-data-entry of electronic records - is also solved by the present invention, as the details related to the particular patient's reason for the visit are completely and accurately electronically transferred to the physician as described by the patient. This has the dual effect of increasing the amount of time the physician can spend with the patient, as the generally sixty to seventy percent of a complete office visit spent on gathering historical information from the patient is eliminated, and providing more thorough documentation for the physician when examining the patient.

INDEPENDENT CLAIM 45 - JOAO IN VIEW OF CAMPBELL

Regarding the rejection of claim 45 based upon Joao in view of Campbell, the foregoing reasons also apply. Claims 33 and 45 are closely related. They contain essentially the same novel elements as described above. In this respect, the same arguments for allowing claim 33 (as outlined above) pertain to claim 45. Therefore, Applicant avers that claim 45 is in condition for allowance and respectfully requests it be allowed as amended herein.

CLAIMS 40 AND 52 - JOAO IN VIEW OF CAMPBELL AND SEGAL

Regarding the rejection of claims 40 and 52 based upon Joao in view of Campbell and further in view of Segal, all of the above arguments are incorporated herein with respect to Joao and Campbell. The Segal patent is directed solely at aiding a clinician (doctor or nurse) in the diagnosis process, not in the data-capturing process. Nowhere is it mentioned to allow the patient directly to provide medical information using their own computer at a time and place of the patient's choosing. Nowhere in Segal is mentioned generating a medical chart note.

Further, while Segal describes a system that "disambiguates between the multiple candidate disease and lead(s) to the correct diagnosis" and gives rationale for doing a particular medical test. Segal does not describe a system that provides condition-specific questions for patients to ask their physician and possible responses to these questions for the physician to

communicate to the patient. Applicant's invention discloses a system wherein key condition-specific questions are generated and transmitted directly to the patient, for answering on the patient's own computer. Segal is again directed toward a diagnosis in that it provides a process for identifying and ranking disease candidates. An editable chart note is never mentioned. Direct data capture is never mentioned.

Therefore, because Joao/Campbell doesn't disclose a system that generates key questions and Segal doesn't disclose providing responses to the questions, it would not have been obvious to one with ordinary skill in the art to provide a method that includes the step of electronically generating an editable chart note for use by a physician that includes using patient information obtained directly and electronically from the patient, and the patient's own computer.

Moreover, the Examiner states on page 13 of the Office Action that "Examiner considers diagnostic/medical tests to include a question or series of questions that are used to query a patient for the purpose of ascertaining their medical condition." This does not take into account the difference between a medical interview and a diagnostic/medical test. They are quite different. A medical interview gains information from the patient about history and current symptoms. A diagnostic test probes for a particular cause, such as a blood test, an X-ray, an MRI, etc. The Examiner is correct in stating that Segal is concerned with obtained diagnostic test results, and couples them to other available medical information **to generate a diagnosis**. The present invention captures medical information (using interviews not medical diagnostic test information) directly from the patient, at the patient's motivation and generates a chart note for use by medical personnel in the normal course of recordkeeping.

Because claim 40 depends from claim 33, and claim 50 depends from claim 45, Applicant believes that these claims are allowable and respectfully requests they are allowed in due course.

Applicant acknowledges that no other references were cited and relied upon.

CONCLUSION

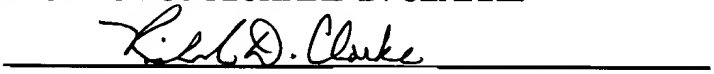
All of the objections and rejections raised by the Examiner have been addressed by Applicant. Attorney for Applicant has carefully reviewed each one of the cited references, namely the Joao, Campbell, and Segal patents, and believes that the amended claims presently on file in the subject application are patentably distinguishable with respect to the prior art, either taken alone or in combination with one another. In view of the amendments to the claims and the remarks submitted herein, Applicant submits that all of the claims on record are in condition for allowance and respectfully requests that a Notice of Allowance be issued in this case in due course.

If it is felt for any reason that direct communication with Applicant's attorney would serve to advance prosecution of this application to allowance, the Examiner is invited to contact the undersigned, attorney of record in this case, Richard D. Clarke, Esq., at one of the listed below numbers or at his below listed e-mail address.

Dated: February 26, 2007

Respectfully Submitted,

LAW OFFICE OF RICHARD D. CLARKE

By 

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